



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/166,701	10/05/1998	ISA ODIDI	SMI-005.01	9432

25181 7590 12/16/2005

FOLEY HOAG, LLP
PATENT GROUP, WORLD TRADE CENTER WEST
155 SEAPORT BLVD
BOSTON, MA 02110

EXAMINER

GEMBEH, SHIRLEY V .

ART UNIT	PAPER NUMBER
----------	--------------

1614

DATE MAILED: 12/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/166,701	Applicant(s) ODIDI ET AL.	
	Examiner Shirley V. Gembeh	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 6 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,7-12 and 28-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,7-12 and 28-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of claims

Claims 1,4,7-12 and 28-33 are pending and rejected.

Claims 2-3, 5-6, 13-22,24-27 have been cancelled,

Response to Amendment

In response to the Office Action dated July 01, 2004, Applicant has provided arguments supporting the patentability of the above claims and has amended claims 1,4,7-12 and 28-33 in the transmittal of a response to July 01, 2004, Office Action Under 37 CFR § 1.111 filed September 23, 2004.

Maintained Claim rejections –35 USC § 103

The rejection of claims 1,4,7-12 and 28-33 under 35 USC § 103(a) over Guley et al., (US 4,309,405) in view of Jain et al., (US 4,610,870) has been maintained for the reasons indicated in the prior Office Action mailed July 01, 2004.

Response to arguments under 35 USC § 103

Applicant's arguments filed September 23, 2004 with respect to the rejection under 35 USC § 103 as they relate to the Guley et al., (US 4,309,405) in view of Jain et al., (US 4,610,870) have been fully considered but they are not persuasive.

Applicant argues that Guley et al., do not specifically teach or suggest the use of combination of HPMC and HEC. At col. 3 lines 44-51, the reference teaches the combination of EC with HPMC. Although the reference did not specifically teach ethylcellulose (EC) to be hydroxyethylcellulose (HEC), it is well within the knowledge of the skilled artisan to modify and use HEC (functionally equivalent) (at col. 3 lines 49-

Art Unit: 1614

51). In fact, Guley et al. suggest/teach the use of HEC in seal coating materials, and the selection of HEC would not change the result as both polymers EC and HEC are in fact water insoluble polymers. Accordingly one of ordinary skill would have been motivated to switch the EC polymer with the HEC because the polymers are used as non-enteric film used in a seal coating with materials that retard any hydration of compressed core. It is well within the skilled artisan to use the combination of both types of polymers, (water insoluble) to allow the drug to be taken without disintegrating in the mouth, and (water soluble) to allow the drug to dissolve by the gastric acid and release the active substance in the gastrointestinal track.

The argument has been fully considered but unpersuasive.

Applicant next argues that the compounds as listed in the Jains' teaching

The hydrocolloid for use in the core will have a viscosity of more than 10,000 centipoises as indicated above, and will preferably comprise cellulose polymers which are cellulose ethers such as methyl cellulose, cellulose alkyl hydroxylates such as hydroxypropyl-methyl cellulose, hydroxypropyl cellulose, hydroxy-methyl cellulose or hydroxyethyl cellulose, cellulose alkyl carboxylates such as carboxymethyl cellulose and carboxyethyl cellulose, and alkali metal salts of cellulose alkyl carboxylates, such as sodium carboxymethyl cellulose and sodium carboxyethyl cellulose, as well as carboxypolymethylene (molecular weight 2.5 to 3.5 million). Preferred are sodium carboxymethyl cellulose, methyl cellulose, hydroxypropylmethyl cellulose and carboxypolymethylene. However, it is to be understood that any hydrocolloid may be employed in the present invention, such as, for example, gum acacia, guar gum, gum tragacanth, gum xanthan, an alkali metal or alkaline earth metal carageenate, alginates, such as alginic acid, ammonium or sodium alginate or mixtures thereof.

(at col. 5 lines 21-40) () are not

interchangeable. Jains' reference does in fact teach of the same types of polymers used in the current claimed subject matter, and as stated in the MPEP 2112.01

Products of identical chemical composition can not have mutually exclusive properties.

Art Unit: 1614

A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658. The skilled artisan would be able to determine the type of polymer to use for a longer duration of controlled release time versus a shorter duration of controlled release drugs because the number of daily doses to be administered is minimized and uniformly released, and the medicine is continually available for absorption into the blood. Per Applicants' definition of a controlled release formulation (as recited on page 2 of the specification) is a device that provides delivery of the pharmaceutically active agents for a predetermined period of time, which is well within the purview of the skilled artisan to determine and is rendered obvious over the prior art of record.

The argument has been fully considered but found unpersuasive.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

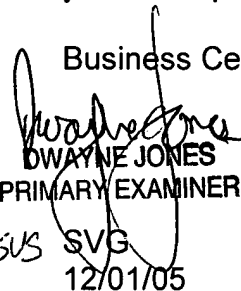
Art Unit: 1614

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembah whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).


DWAYNE JONES
PRIMARY EXAMINER
SVS SVG
12/01/05